



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 866

[Docket No. FDA-2013-N-1662]

Medical Devices; Immunology and Microbiology Devices; Classification of John Cunningham Virus Serological Reagents

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying John Cunningham Virus (JCV) serological reagents into class II (special controls). The Agency is classifying the device into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of the device.

DATES: This order is effective [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. The classification was effective January 20, 2012.

FOR FURTHER INFORMATION CONTACT: Haja Sittana El Mubarak, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5519, Silver Spring, MD 20993-0002, 301-796-6193.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976), generally referred

to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II, or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act, to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807) of the regulations.

Section 513(f)(2) of the FD&C Act provided a procedure by which a person may request that FDA classify a device under the criteria set forth in section 513(a)(1). The person submits a premarket notification under section 510(k) of the FD&C Act for a device that has not previously been classified and, within 30 days of receiving an order classifying the device into class III under section 513(f)(1) of the FD&C Act, the person requests a classification under section 513(f)(2). In response to a request to classify a device under the procedure provided by section 513(f)(2) of the FD&C Act, FDA will classify the device by written order within 60 days. This classification will be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing this classification.

In accordance with section 513(f)(1) of the FD&C Act, FDA issued an order on December 22, 2011, classifying the STRATIFY JCVTM antibody enzyme-linked immunosorbent assay (ELISA) into class III because it was not substantially equivalent to a device that was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, or a device which was subsequently reclassified into class I or class II. On

January 5, 2012, Focus Diagnostics, Inc., submitted a request for de novo classification of the STRATIFY JCVTM antibody ELISA under section 513(f)(2) of the FD&C Act. The manufacturer recommended that the device be classified into class II.

In accordance with section 513(f)(2) of the FD&C Act, FDA reviewed the request for de novo classification in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act. FDA classifies devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the request, FDA determined that the device can be classified into class II with the establishment of special controls. FDA believes these special controls will provide reasonable assurance of the safety and effectiveness of the device.

The device is assigned the generic name John Cunningham Virus serological reagents, which are devices that consist of antigens and antisera used in serological assays to identify antibodies to JCV in serum and plasma. The identification aids in the risk stratification for the development of progressive multifocal leukoencephalopathy in multiple sclerosis and Crohn's disease patients undergoing natalizumab therapy. These devices are for adjunctive use, in the context of other clinical risk factors for the development of progressive multifocal leukoencephalopathy.

FDA has identified the following risks to health associated with this type of device and the measures required to mitigate these risks:

Table 1.--Identified Risks to Health and Mitigation Measures

Identified Risks to Health	Mitigation Measures
False positive results	Device Description Performance
False negative results	Device Description Performance
Failure to perform as indicated or an error in the interpretation of the results	Labeling

FDA believes that the measures set forth in the special controls guideline entitled "Class II Special Controls Guideline: John Cunningham Virus Serological Reagents" are necessary, in addition to general controls, to mitigate the risks to health described in table 1.

Therefore, on January 20, 2012, FDA issued an order to the petitioner classifying JCV serological reagents into class II. FDA is codifying this device type by adding 21 CFR 866.3336.

II. 510(k) Premarket Notification

Following the effective date of this final classification order, any firm submitting a 510(k) premarket notification for this device type will need to comply with the special controls.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. For this type of device, FDA has determined that premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device. Therefore, this type of device is not exempt from premarket notification requirements. Persons who intend to market this type of device must submit to FDA a premarket notification, prior to marketing the device, which contains information about the JCV serological reagents they intend to market.

III. Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Paperwork Reduction Act of 1995

This final administrative order establishes special controls that refer to previously approved collections of information found in other FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in part 807, subpart E, regarding premarket notification submissions have been approved under OMB control number 0910-0120; and the collections of information in 21 CFR part 801 and 21 CFR 809.10 have been approved under OMB control number 0910-0485.

List of Subjects in 21 CFR Part 866

Biologics, Laboratories, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 866 is amended as follows:

PART 866--IMMUNOLOGY AND MICROBIOLOGY DEVICES

1. The authority citation for 21 CFR part 866 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

2. Section 866.3336 is added to subpart D to read as follows:

§ 866.3336 John Cunningham Virus serological reagents.

(a) Identification. John Cunningham Virus serological reagents are devices that consist of antigens and antisera used in serological assays to identify antibodies to John Cunningham

Virus in serum and plasma. The identification aids in the risk stratification for the development of progressive multifocal leukoencephalopathy in multiple sclerosis and Crohn's disease patients undergoing natalizumab therapy. These devices are for adjunctive use, in the context of other clinical risk factors for the development of progressive multifocal leukoencephalopathy.

(b) Classification. Class II (special controls). The special control for this device is the FDA guideline document entitled "Class II Special Controls Guideline: John Cunningham Virus Serological Reagents." For availability of the guideline document, see § 866.1(e).

Dated: January 16, 2014.

Leslie Kux,

Assistant Commissioner for Policy.